

Application of: Ko-Pen Wang  
Serial No.: 10/693,646  
Filed: October 27, 2003  
Reply to Office Action of January 10, 2006

REMARKS

The undersigned would first like to express thanks to Examiners Apanius and Hindenburg for conducting an interview in this application. The invention was discussed during that interview along with Dr. Wang's prior inventions, as well as a description of how the present invention is used.

By way of this Response, claims 20-23 have been cancelled and claims 1, 7, 8, 13-19, 24 and 25 have been amended. It is believed that the amendments fully correct the rejections made under 35 U.S.C. § 112 and withdrawal of those rejections is respectfully requested.

The noted paragraphs of the specification have also been corrected, as suggested, and approval thereof is also respectfully requested.

Claims 1-25 were rejected under 35 U.S.C. § 102 as being anticipated by Wang, U.S. Patent No. 4,966,162 (hereafter '162). This rejection is traversed and is not believed to be well founded.

In conducting tissue sampling from within the lungs it is first necessary to correctly position the sampling device in the correct position. The lungs have many branches each with many twists and turns. Consequently, it is important to be able to follow those twists and turns by having a very flexible end on the sampling device. However, by the same token, once in position it is equally important to have enough rigidity to permit the sampling and to allow the device to be pushed into tissue.

The invention employs a novel distal end structure that provides both the initial flexibility to get the distal end into the desired position, having followed many turns in small and tight passageways within the lung, as well as the ability to turn that flexible distal end into a much more rigid structure prior to sampling.

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This is accomplished by employing a spring having two sections, a distal section and a proximal section, with the proximal section having uncompressed and compressed states. A stylet is connected to a portion of the proximal section and a proximal end of the sampling member, for example a needle or some other member, is connected to the distal portion. This permits several levels of flexibility to be achieved between the times when the sampling member is retracted and extended. First, when the sampling member is retracted the proximal section will be uncompressed and be very flexible, the distal section will have its level of flexibility, and the stylet will be located primarily within the uncompressed proximal section. The stylet can extend into the distal section but not far. That arrangement makes the distal end structure of the device very flexible.

When the distal end of the sampling member is extended out of the distal end structure in a first extended position, the proximal section will still remain uncompressed, the distal section will have been moved toward the distal end of the device and the stylet will remain in its previous position. The distal end structure is flexible but less so than in the previous retracted position.

In a second extended position the proximal section will be compressed and the stylet will now be positioned through a substantial portion of the distal section, and in some cases it can be pushed to be within, but not blocking fluid flow through, the proximal end of the sampling member. Compression of the proximal section and the movement of the stylet into the distal section will make the distal end of the device more rigid and much less flexible than either of the two previous levels of flexibility.

Dr. Wang's previous '162 patent does not disclose this invention, either structurally or functionally. The '162 patent provides gaps 266 and 318 to serve as passageways for the fluid and vacuum to flow. The '162 specification notes that gap 266 does not prevent spring 252 from being loaded axially, and those gaps should not be

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closed (See, col. 10, lines 63-64). Next, there is no suggestion for dividing spring 302, shown in Fig. 13, into distal or proximal halves, the stylet 308 passes freely through the conduit 218, through spring 302 and through and out needle 304. It is not connected to any thing, and not to any proximal portion of spring 302. Further, it is not being used for making the tip rigid but rather to ease penetration of the hollow needle into tissue. While the Examiner states "a second spring section (proximal half of 302 including multiple gags 318) coupled to the stylet..." as what the '162 patent discloses, that is not the case. Were that true the stylet 308 would not be able to be pushed out like it is through spring 302 and needle 304 in Fig. 13, nor would it be retractable while maintaining spring 302 in a compressed condition to hold needle 304 in its extended position.. The Examiners attention is directed to col. 11, lines 49-51 and to col. 12, lines 14-22.

The '162 patent does not discuss, disclose or suggest a variety of levels of flexibility, the concept of having the distal end of the device be changeable from being very flexible and then rigid, nor how one can employ a variety of spring conditions to provide those varying levels of flexibility, nor the use of an inner stylet to work with the springs.

It is respectfully submitted that the claims now under examination, 1-19, 24 and 25 define patentable over the '162 patent and are in allowable condition. Notice to that effect is respectfully requested.

The provisional rejection on the basis of non-statutory double patenting is also traversed. The Examiner based that rejection on claims 1, 5, 7, 14 and 16 in the co-pending companion application Serial o. 10/693,645. The claims pending in that application have been amended and in fact claims 5, 7 and 14 have been amended in a manner that is believed will preclude the rejection. Further claim 16 in that application has been cancelled.

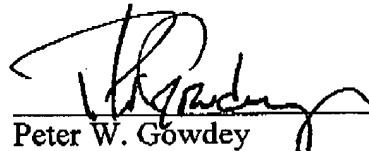
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Consequently, withdrawal of the double patenting rejection is respectfully requested.

Since all of the outstanding rejections and objections have been overcome, it is believed that this application is now in allowable condition and notice thereof is respectfully requested.

Respectfully submitted,

DAVIDSON, BERQUIST,  
JACKSON & GOWDEY, L.L.P.



Peter W. Gowdey  
Registration No. 25,872

CUSTOMER NUMBER

42624

Davidson Berquist Jackson & Gowdey, LLP  
4300 Wilson Boulevard, 7th Floor  
Arlington, VA 22203  
Ph: 703-894-6400  
Fax: 703-894-6430